

REMARKS

Applicant respectfully requests reconsideration. Claims 180-206 were previously pending in this application. No claims have been amended, added, withdrawn or canceled. As a result, claims 180-206 remain pending for examination with claims 180, 189, 192, 198, 201 and 205 being independent claims. No new matter has been added.

Interview Summary

Applicant thanks Examiner Aeder for the courtesy of a telephone interview with Applicant's Assignee's representatives on Wednesday, April 15, 2009. During the interview, Applicant's Assignee's representatives discussed with the Examiner the double patenting rejection based upon copending Application No. 10/260,708. Applicant's Assignee's representatives stated that the subject matter of the pending claims of the instant application and the subject matter of the allowed claims of Application No. 10/260,708 had been previously characterized by the United States Patent and Trademark Office (USPTO) as distinct inventions. The Examiner remarked that the double patenting rejection would be withdrawn. Arguments for overcoming the rejection under 35 U.S.C. §103 were also discussed, although no agreement was ultimately reached.

Double Patenting Rejection

The Examiner provisionally rejected claims 180-206 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3, 10, 11, 143, 162, 163, 191, 192 and 195 of copending Application No. 10/260,708 (the " '708 application").

As discussed during the interview with the Examiner, the USPTO in the Restriction Requirement dated July 13, 2005 of the '708 application deemed the subject matter of the pending claims of the instant application and the subject matter of the allowed claims of the '708 application to be "distinct inventions". As indicated above, during the interview, the Examiner indicated that this rejection would be withdrawn. Accordingly, it is believed that this rejection is now moot.

Rejections Under 35 U.S.C. §103

Claims 201-206 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Dumas et al. (EP 1 033 401 A2) ('Dumas') in view of Altman et al. (Science, 1996, 274:94-96) ('Altman'). The Examiner states that Dumas teaches an isolated polypeptide that has the sequence set forth in SEQ ID NO: 4557, which comprises a sequence set forth as a fragment of SEQ ID NO: 55 of the instant application. The Examiner states that Dumas does not specifically teach a composition comprising said polypeptide complexed to a class I MHC costimulatory molecule and a pharmaceutical carrier but asserts that Altman makes up for this deficiency. The Examiner asserts that one of ordinary skill in the art at the time the invention was made would have been motivated to produce compositions comprising the polypeptide of Dumas according to the methods of Altman, because Dumas teaches that *said polypeptide* is to be evaluated for its effects on cytotoxic lymphocytes. The Examiner further asserts that one of ordinary skill in the art would have had a reasonable expectation of success, because Dumas teaches said polypeptides and Altman teaches polypeptides conjugated to a class I MHC costimulatory molecule and a pharmaceutical carrier.

Applicant respectfully disagrees. It is Applicant's position that the pending claims are not obvious in view of the cited references and that the Examiner has failed to establish a proper *prima facie* case of obviousness.

The analysis supporting a rejection under 35 U.S.C. §103 "cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). (original citations omitted). In Takeda Chemical Industries, LTD. v. Alphapharm PTY., LTD., 492 F.3d 1350 (Fed. Cir. 2007), which was decided post-KSR, Alphapharm asserted that compounds claimed in a Takeda patent were invalid as obvious in view of a lead compound which was disclosed in the prior art, and which parties agreed was the closest prior art compound. Alphapharm argued that the prior art would have led one of ordinary skill in the art to select the lead compound from among a genus of fifty-four compounds, which had been specifically identified in a patent document disclosing millions of other related compounds, and modify that lead compound with two obvious chemical changes to arrive at the compound claimed in the Takeda patent, thereby rendering it invalid. *Id.* at 1357.

The Federal Circuit was not persuaded by Alphapharm's assertions on multiple grounds and upheld the district court's ruling that the claimed compounds were unobvious in view of the prior art, reasoning, in part, that when the prior art discloses a vast number of compounds as possible lead compounds (starting points) there must be something in the prior art to "narrow the possibilities" to the particular lead compound that is to form the basis of an obviousness rejection. *Id.* at 1358.

Similar to the failure of Alphapharm's obviousness assertion, this rejection fails as there is nothing in the prior art cited by the Examiner to "narrow the possibilities" to the particular lead compound (in this case the polypeptide of SEQ ID NO: 4557). There is nothing in the prior art that would direct one of ordinary skill in the art to select the polypeptide of SEQ ID NO: 4557 from among the more than 4000 other polypeptides also disclosed in Dumas. The Examiner states that Dumas teaches that "said polypeptide" – referring to the polypeptide of SEQ ID NO: 4557 – is to be evaluated for its effects on cytotoxic lymphocytes. However, in this context, Dumas only refers to "proteins or polypeptides" generically and does not identify any polypeptide or subset of polypeptides specifically, let alone the polypeptide of SEQ ID NO: 4557. Therefore, as in Takeda, the claims are not obvious in view of the cited references, because there is nothing in the prior art that would have led the skilled artisan to have narrowed the possibilities to the polypeptide of SEQ ID NO: 4557 from among the more than 4000 other polypeptides also disclosed in Dumas.

In addition, the Examiner asserts that claims 205 and 206 are obvious in view of the teachings of Dumas in view Altman. However, the Examiner has failed to provide any reason why one of ordinary skill in the art would select a polypeptide of Applicant's claims and combine it with an adjuvant, cytokine, or a costimulatory molecule in a composition.

Finally, Applicant notes for the record that the Examiner did not correctly characterize the subject matter of claim 202. Claim 202 is directed to the composition of claim 201, wherein the fragment is at least 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 75 or 100 amino acids in length.

In view of the foregoing, reconsideration and withdrawal of this rejection is respectfully requested.

Allowable Subject Matter

Applicant respectfully thanks the Examiner for indicating that claims 180-200 have been allowed.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. L0461.70156US00.

Respectfully submitted,

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